Medicines Safety Newsletter

Issue 5 – July 2019

Welcome to our Summer Edition!

Summer is here and so is the latest edition of our Medicines Safety Newsletter. Our summer edition includes a number of important patient safety updates, tips to help minimise patient safety errors, and a round-up of some of the errors reported into the Community Pharmacy West Yorkshire office during the last quarter. We hope you find it both informative and useful.

Patient safety is a fundamental consideration for all front line healthcare professionals. Around 1.1 billion prescriptions are supplied each year in primary care, and whilst we don't set out to make an error when delivering these medicines, even in the safest healthcare system in the world, mistakes do occur.

All community pharmacists, pharmacy technicians and pharmacy support staff will recognise the importance of safely dispensing medication and providing appropriate advice to patients and the public. While things run seamlessly most of the time, it is important to learn the lessons when something does go wrong. The aim of our newsletter is to promote and support safer practice by highlighting to pharmacy teams medication incidents that have occurred both locally and nationally and sharing the lessons that have been learnt to help prevent these from happening again. Please continue to feed in by letting us know about any significant medicines related incidents that have occurred in your workplace – see contact details at the end.

We hope that you all have a fantastic (and safe) summer and thank you again for your continued support.

Share and Learn

You will already be reporting patient safety incidents nationally, (to the NRLS), and/or via your local reporting system. **Please continue to follow your company's SOP for incident reporting,** however, it would be fantastic if you could also help us to support all our West Yorkshire pharmacy teams by "sharing the learning".

If you have come across or been involved in a dispensing OR prescribing error (or other medicines related incident) it is likely that this may not be a "one off". The chances are that this may have already happened at the pharmacy over the road and may yet happen at the pharmacy in the next town. By reporting incidents and sharing the learning you can prevent this from happening and potentially save a patient from harm.

Report it – for everyone's sake!

If you wish to share any medicines safety incidents, (and your learning), with other West Yorkshire pharmacies via this newsletter please complete the Report, Learn, Share, Act, Review template (click here) and return to info@cpwy.org.

All reports will be treated completely anonymously and no details of who submitted the report will be shared outside of the Community Pharmacy West Yorkshire team. Please remember to NOT send any patient identifiable details.

Just Ask: Could it be Sepsis?

We have all seen too many news stories about sepsis and the tragic consequences sepsis can have if not spotted early.

Previously referred to as blood-poisoning, sepsis is the body's reaction to an infection in which the body kills its own tissues and organs. It is a potentially life-threatening condition which affects 250,000 people every year in the UK and kills more people than bowel, breast and prostate cancer combined. Tragically many of these deaths are preventable.

AWARENESS CAN AND DOES SAVE LIVES, so it is important that as health care professionals, you and your pharmacy teams are able to spot the signs and symptoms of sepsis so that appropriate medical care is sought without delay if sepsis is suspected. Early recognition, diagnosis and treatment dramatically improves outcomes from sepsis.

So, what causes Sepsis?

Sepsis can be triggered by any infection, but most commonly it occurs in response to bacterial infections of the lungs, urinary tract, abdominal organs or skin and soft tissues. Everybody is potentially at risk of developing sepsis from minor infections, but some people are more at risk. These include:

- Babies < 1 year
- People > 75 years
- People who are frail

- Diabetics
- People with weak immune systems
- People having chemotherapy
- People who have had recent surgery
- Women who have just given birth or recently been pregnant (including those who have had a miscarriage or abortion).
- People who have had a recent serious illness.

Patients with known infections are vulnerable, their sepsis symptoms are often misinterpreted as self-limiting conditions such as flu or gastroenteritis, potentially resulting in delayed treatment. It's highly unpredictable, and the speed and severity vary from case to case. In some cases, it can develop over the course of several days, in others, it can simply be a matter of hours.

Sepsis does not discriminate and can strike at any time.

Signs and Symptoms

The Sepsis Trust has compiled a list of the six most common symptoms to be aware of:

- **S** lurred speech or confusion
- **E** xtreme shivering or muscle pain
- **P** assing no urine (in a day)
- **S** evere breathlessness
- **I** t feels like you're going to die
- **S** kin mottled or discoloured

Common symptoms in children include:

There are handy summaries of these symptoms which can be downloaded and printed. See sepsis in adults here. See sepsis in children here.

Further Information & Learning

Watch Think Sepsis here.

The NICE Clinical Knowledge Summary (CKS) for managing feverish children under 5 years has been updated to include a traffic light system which covers the risk assessment of an infant or child with fever. See the website here: https://cks.nice.org.uk/feverish-children-risk-assessment

JUST ASK "COULD IT BE SEPSIS?"

Hormone Replacement Therapy (HRT)

We have been made aware of a number of incidents which have occurred locally involving HRT. In all of the reported incidents the prescriber had asked for advice about alternative products (due to stock shortages) and the community pharmacist has recommended an alternative, but not equivalent HRT patch.

In the two more serious reports, Evra, (a contraceptive patch) was recommended as an alternative for Evorel patches. Unfortunately, based on this advice, a GP went on to prescribe Evra and the patient using the patches later developed thrombophlebitis and subsequently a pulmonary embolism. **Please do not recommend Evra as an alternative HRT patch. It is not indicated for post-menopausal women and is not intended for use as HRT.**

Although the responsibility for safe and appropriate prescribing rests with the prescriber, if you are asked to suggest an alternative product/recommend a change to a prescription, you must ensure that your recommendation is appropriate for each patient and within your scope of competency to recommend.

You must consider the clinical indication for the drug to ensure that any recommended alternative is appropriate (and licenced) and that the form and dose are equivalent (e.g. that the dose and combination of hormones in an alternative HRT are the same as was originally prescribed).

The type of HRT used is determined by the presence or absence of a uterus, menopausal status, past medical history and current medication. Generally, women who have had a hysterectomy are offered oestrogen replacement therapy whilst those with an intact uterus are prescribed oestrogen with a progestogen given sequentially or continuously.

As there are a number of factors to consider when recommending alternative HRT products, (e.g. is the patient on combined or oestrogen-only HRT? Are they on sequential or continuous HRT?), if you are asked about alternative products it may be better to supply a list of products that you have in stock and make it clear in your communication with the practice that you do not have enough information to make a recommendation for each individual patient but this is a list of the HRT products currently stocked.

The current shortages of HRT products seems to be linked to a number of errors reported nationally with the NPA MSO Medicines Safety Report for quarter 1 2019 recording that HRT preparations are "becoming one of the most common causes of look-alike, sound-alike errors in the first 3 months of 2019, as patients are being switched to alternative preparations in the interim". HRT preparation errors have included Elleste Solo/Elleste Duet, Femoston/Femoston-Conti and Kliofem/Kliovance

TYPES OF HRT

There are two different types of HRT:

- **Oestrogen only (no progestogen)** – generally offered to women who have had a hysterectomy (without a uterus).
- **Combined HRT (oestrogen and progestogen)** – for women with an intact uterus. This can be given in two ways:
  o Continuous combined HRT – oestrogen and progesterone, taken together daily (one a day) for 28 days, this means that there will be no withdrawal bleeds.
  o Sequential HRT – oestrogen only for the first 14 days then both hormones for the second 14 days. This usually results in monthly withdrawal bleeds.

Look-Alike Sound Alike Medicines (LASA Medicines)

The most common LASA errors reported in Quarter 1 of 2019 according to the NPA's Medication Safety Report were:

Common LASA errors	
Amlodipine	Amitriptyline
Gabapentin	Pregabalin
Atenolol	Allopurinol
Atorvastatin	Amlodipine
Bisoprolol	Bendroflumethiazide
Enalapril	Escitalopram

There are a number of risk minimisation measures which can be applied to try and reduce the likelihood of LASA errors occurring, including physical separation and visual warnings.

Some pharmacy teams move one of the LASA pair into a 'high risk' medicines area in the dispensary, others move one of the LASA pair down to 'Z'.

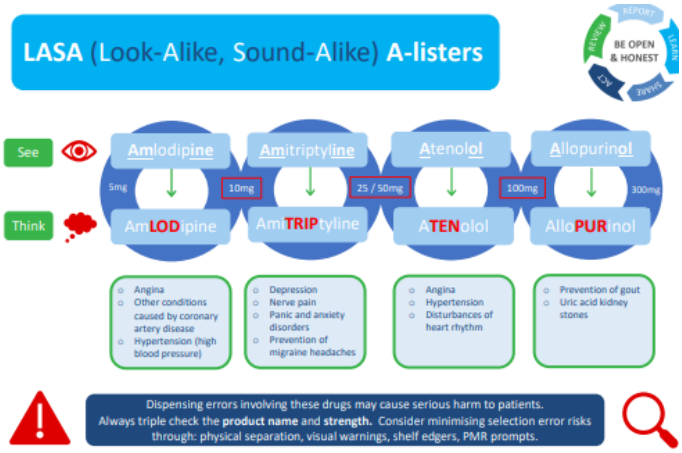
However, every patient safety incident is caused by a combination of contributory factors, including human factors, and therefore a combination of risk minimisation measures is usually necessary. It is often the checking procedure itself which can allow LASA errors to occur. Too often the prescription is checked against the applied dispensing label, rather than the pack itself.

Remember to be extra vigilant when dispensing medicines with commonly confused drug names to ensure that the intended medicine is supplied and to follow local and professional guidance in relation to checking the right medicine has been dispensed. This should include checking:

✓ **Right medicine**
✓ **Right patient**
✓ **Right dose**
✓ **Right route**
✓ **Right time**

There are a series of useful one-page resources available on the Community Pharmacy Patient Safety Group website which pharmacy teams may find helpful in their safety huddle discussions around LASA errors. These can be downloaded here.

There is also a LASA training video available which explains the risks associated with mixing up LASA medicines as well as some of the risk-minimising actions that their pharmacy teams have put in place. This video is a great way to support pharmacy students or pre-registration pharmacists in their learning, but it can also be used by practising pharmacy teams to consider any actions that could be taken in their pharmacy to reduce the likelihood of errors involving LASA medicines occurring. This is available here.



MHRA DRUG SAFETY UPDATE:

ORAL LIDOCAINE-CONTAINING PRODUCTS FOR INFANT TEETHING: ONLY TO BE AVAILABLE UNDER THE SUPERVISION OF A PHARMACIST

Oral lidocaine-containing products for infant teething are only to be available under the supervision of a pharmacist so that parents and caregivers can receive guidance about managing infant teething symptoms. See quick reference guide for pharmacists here.

Non-medicinal options such as a teething ring or massaging the gum should be the first line for relieving infant teething symptoms, and lidocaine-containing products should only be used when simple measures have failed to provide sufficient relief.

SUMMARY OF ADVICE FOR PHARMAY TEAMS:

- All oral lidocaine-containing products with an infant teething indication are becoming pharmacy medicines.
- Pharmacists should only recommend use of these products when local non-medicinal treatments such as a teething ring or massaging the gum have failed to provide sufficient relief.
- If oral lidocaine-containing products are to be used, remind parents and caregivers to read the advice in the Patient Information Leaflet carefully, especially for dose and administration, and to seek medical attention if their child's condition does not improve.
- Advise parents and caregivers that other lidocaine products authorised in adults or for other conditions such as mouth ulcers should not be used for treatment of infant teething pain.

- Sugar-free paracetamol or ibuprofen suspensions, administered according to the approved indication and dose for weight and age, may also be considered for the relief of teething symptoms.

The NPA has produced a useful poster reminding pharmacy teams of these changes. See here.

MHRA DRUG SAFETY UPDATE:

RIVAROXABAN: REMINDER THAT 15 MG AND 20 MG TABLETS SHOULD BE TAKEN WITH FOOD

The MHRA has received a small number of reports suggesting lack of efficacy (thromboembolic events) in patients taking 15 mg or 20 mg rivaroxaban on an empty stomach. Please remind patients to take 15 mg or 20 mg rivaroxaban tablets with food.

SUMMARY OF ADVICE FOR HEALTHCARE PROFESSIONALS

- Remind patients to take rivaroxaban 15 mg or 20 mg tablets with food
- For patients who have difficulty swallowing, tablets can be crushed and mixed with water or apple puree immediately before taking; this mixture should be immediately followed by food
- Rivaroxaban 2.5 mg and 10 mg tablets can be taken with or without food

The full (July 2019) Drug Safety Update can be downloaded here.

MHRA DRUG SAFETY UPDATE:

YELLOW CARD: PLEASE HELP TO REVERSE THE DECLINE IN REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS

Reporting suspected adverse drug reactions (also termed ADRs) to the Yellow Card Scheme helps the MHRA to monitor the safety of medicines and improve patient safety.

2018 saw a fall in reporting of suspected adverse drug reactions (ADRs) to the Yellow Card Scheme from key reporter groups, including GPs and community pharmacists. Every Yellow Card report counts, and a few minutes taken by you or your patient to report can make a lifetime of difference for others.

What should I report?

Yellow Cards can be used for reporting suspected adverse drug reactions to medicines, vaccines, herbal or complementary products, whether for self-medication or prescribed. This includes suspected adverse drug reactions associated with misuse, overdose, or medication errors, or from use of unlicensed and off-label medicines. You should report all suspected adverse drug reactions that are:

- Serious, medically significant, result in harm, or associated with medication errors where harm occurs. Serious events are fatal, life-threatening, a congenital abnormality, disabling or incapacitating, or resulting in hospitalisation
- Associated with newer drugs and vaccines (▼), irrespective of whether they are serious or not. If in doubt whether to report or not, please complete a Yellow Card.

How can I complete a Yellow Card?

- Online at https://yellowcard.mhra.gov.uk/
- Via the Yellow Card app available in the Apple App Store or Google Play Store
- Through SystmOne, Vision, and MiDatabank clinical IT systems
- By emailing yellowcard@mhra.gov.uk or by downloading printable reporting forms from the Yellow Card website and sending them freepost to 'Yellow Card'
- By completing Yellow Card forms in the BNF, NPF, MIMS, or PAGB OTC directory
- By calling the Yellow Card reporting line on 0808 100 3352.

Don't wait for someone else to report it!

Talk to your patients about side effects and the Yellow Card Scheme (patient reports now account for the highest reporting group). If you have a screen in your patients' waiting area why not raise awareness of the scheme by downloading this useful animation here.

MHRA MEDICAL DEVICE ALERT:

FREESTYLE LIBRE FLASH GLUCOSE SENSOR – USE OF BARRIER METHODS TO REDUCE SKIN REACTIONS TO THE SENSOR ADHESIVE

Just a quick reminder of a medical device alert which was issued by the MHRA earlier this year which reported that some users of the device were experiencing sensitivity to the adhesive, (which keeps the sensor attached), and were applying creams, patches or sprays under the sensor to reduce the skin reaction. These barrier methods have not been tested by the manufacturer and may therefore affect the performance of the device.

Please refer to the full alert here.

INCIDENT SHARING

The following are summaries of some of the medicines safety incidents which have been reported from our local pharmacy teams.

THANK YOU to everyone who has shared details of their incidents with us. This will hopefully benefit other local pharmacies by helping to avoid the same errors happening again, and thus potentially helping to avert patient harm.

- **Wrong drug/medicine – Lorazepam/Loprazolam (LASA)**
  REPORT - *Loprazolam 1mg tablets were dispensed instead of the prescribed Lorazepam 1mg tablets. Unfortunately, the patient, who was terminally ill, took the incorrect tablets and subsequently passed away. The error was adjudged not to have been the cause of the patient's death but that it had affected the pace of the patient's end of life.*
  LEARN & SHARE – *The 2 drugs are examples of LASA medication. The chance of a patient identifying an error is reduced when LASA medication is involved. In the dispensary, where the error occurred, the 2 drugs were next to each other on the shelf. The shelves were untidy and the use of 'check similar name' stickers were not in place.*
  ACT – *The following actions have now been implemented:*
  - ✓ *Use 'check similar name' stickers to raise awareness and minimise risk*
  - ✓ *Physically separate the drugs on the shelves*
  - ✓ *When dispensing/checking a prescription for either Lorazepam or Loprazolam staff need to be aware of the other drug and make sure it is the correct one being dispensed.. Although this incident involved Lorazepam/Loprazolam, similar consideration should be applied to Lormetazapam.*
  - ✓ *Think of acronyms/methods of distinguishing between the 2 drugs (the pharmacy involved in the error use the following to raise awareness: "Lorazepam – more commonly used and has 9 letters. Loprazolam – less commonly used and has 10 letters (2 Ls for less common)"*

- **Wrong drug/medicine – Humalog Insulin/Humulin 1 Insulin (LASA)**
  REPORT – *A 14-year old child was prescribed Humalog Insulin but incorrectly dispensed Humulin I. The patient self-administered the incorrect insulin several times over a 3-day period before the error was spotted by the diabetes nurse. The patient had elevated blood glucose, a general malaise and excessive thirst. The incident was classed as a significant event and a significant event analysis completed.*
  LEARN & SHARE – *These insulin products are examples of LASA medication. The dispenser involved was new to pharmacy and had limited experience with insulin preparations. Insulin is a high-risk medicine with additional checks required at hand-out (as documented in the pharmacy SOP). The dispenser's unfamiliarity with insulin may have made the check at hand-out less effective as may the fact that the patient was a child who self-administers. The pharmacist involved was a locum who was unfamiliar with the branch, the patient, and products used locally.*
  ACT – *LASA medication positioning was reviewed in the fridge. The branch manager completed a full team huddle to discuss the incident and share the learning and a 1:1 held with the dispenser. The branch manager undertook a period of supervision for the following 4 weeks (during the tasks of dispensing and transfer of prescriptions to patients). The locum pharmacist was contacted to make them aware of the incident and to prompt them to reflect on their accuracy checking procedure.*

- **Wrong dose – Colcichine Overdose**
  REPORT – *A prescription was received for colcichine 1mg – dose 6 per day. Colcichine 500mcg tablets were dispensed, labelled with a dose of 12 per day. The patient spent 4 days in hospital after presenting with sickness and diarrhoea after taking 14 tablets over 24 hours.*
  LEARN & SHARE – *This was a prescribing error made by the GP, (BNF dose = 500mcg 2-4 times a day until symptoms are relieved. No more than 6mg (12 tablets) should be taken as a course of treatment). The pharmacist's lack of knowledge of the dosage and other factors led to the pharmacist not spotting the overdose:- the incident happened during the pharmacy's busiest period, (between 4-5), and the pharmacy was short staffed that day (2 members of staff, including the main dispenser were off). We have learnt not to rush any prescriptions and to always double-check the dose, checking with the prescriber when any uncertainty exists.*
  ACT – *The following actions have been implemented:*
  - ✓ *The shelf has been labelled where the drug is stocked to state "MAX DAILY DOSE = 2-4 & MAX COURSE = 12 TABLETS".*
  - ✓ *A review of high-risk drugs has been undertaken and the shelves labelled with reminders about monitoring requirements, required dose etc.*
  - ✓ *A company memo was emailed to all managers of other branches to cascade the information and implement the same procedures (e.g. labelling of shelving).*
  - ✓ *The pharmacist has written a reflective CPD account and updated themselves on the condition, treatments available and counselling required.*

- **Wrong drug – Semaglutide/Somatuline**
  REPORT – *Patient prescribed semaglutide 0.5mg/0.37ml which we needed to order in. We also received some somatuline LA 30mg injection in the same order, which was then dispensed (instead of the semaglutide) by a trainee dispenser and checked by the ACT.*

The pharmacist noticed the error after delivery to the patient and rectified before the patient used the incorrect item.

LEARN & SHARE – *When dispensing and checking unfamiliar drugs always take more care (and take additional care when checking the work of a trainee). We were expecting the item to come in so when it did, we didn't look closely enough at what was delivered (we were short staffed that day due to holiday which put everyone under more pressure).*

ACT – *The following actions have been implemented:*

- ✓ *Everyone was made aware of the incident and all staff told to take extra care when dispensing unusual items.*
- ✓ *To double check any unusual items received in the order match the prescription.*

Bitesize News

- **REMINDER — Valproate Pregnancy Prevention Programme.** Following publication of the strengthened regulatory position on sodium valproate prescribing in women and girls please be advised that updated guidance and patient resources, (including the updated annual risk acknowledgement form) can be found here. Pharmacy teams are reminded that a statutory patient information leaflet must always be provided with a medicine containing valproate. Additional copies of the patient information leaflet of valproate-containing medicines are available to download here.
- **Minor Illness Resource Hub** - PSNC has collated a useful one-stop resource hub to support community pharmacy teams in managing minor illness. This includes identifying any red flag symptoms which may suggest the condition is not minor.
- **Hydrocortisone muco-adhesive buccal tablets**: **should not be used off label for adrenal insufficiency in children due to serious risks.** Hydrocortisone muco-adhesive buccal tablets are indicated only for local use in the mouth for aphthous ulceration and should not be used for treating adrenal insufficiency. Substitution of licensed oral formulations of hydrocortisone with muco-adhesive buccal tablets can result in insufficient cortisol absorption and, in stress situations, life-threatening adrenal crisis. Prescribers and pharmacists should only consider use of licensed hydrocortisone products for adrenal replacement therapy. See December's Drug Safety Update here for further information.
- **Pregabalin – guidance for people working with users.** Pregabalin is predominantly used for the treatment of epilepsy and for anxiety disorders. It can be misused either through overuse of the prescribed amount, or through recreational use, and in the last few years, there has been a marked increase in the number of people being prescribed pregabalin and sadly the number of deaths caused by overdose/misuse has also increased. Extern have produced a handy booklet, primarily to support anyone who works with people who use pregabalin that is not prescribed to them, however, it may also be useful for people who overuse their prescribed amount. It provides important information about the uses of Pregabalin, common side effects and withdrawal symptoms and gives suggestions on how to engage with people about their Pregabalin use. Download the booklet here.
- **Tapentadol (Palexia): risk of seizures and reports of serotonin syndrome when co-administered with other medicines.** As for all opioid medicines, tapentadol can induce seizures and should therefore be prescribed with care in patients with a history of seizure disorders or epilepsy. Tapentadol may increase seizure risk in patients taking other medicines that lower seizure threshold, for example, antidepressants such as SSRIs, SNRIs, tricyclic antidepressants, and antipsychotics. Serotonin syndrome has been reported when tapentadol is used in combination with serotoninergic antidepressants. Withdrawal of the serotoninergic medicine, together with supportive symptomatic care, usually brings about a rapid improvement in serotonin syndrome. See January's Drug Safety Update here for further information.
- **Yellow Card App: download the updated app to receive the latest MHRA safety news and report suspected side effects, including in pregnancy.** The app is available for download free of charge from iTunes Yellow Card for iOS devices or Playstore Yellow Card for android devices.

Drug Safety Updates (MHRA)

Contents of recent Drug Safety Updates are listed below. Where this has particular relevance to community pharmacy this has been highlighted in red and a summary of the advice provided. For further information about any of these updates refer to MHRA Drug Safety Updates in full by clicking here.

May 2019 (click here for May's Drug Safety Update)

- Lemtrada (alemtuzumab) and serious cardiovascular and immune-mediated adverse reactions: new restrictions to use and strengthened monitoring requirements.
- Tofacitinib (Xeljanz▼): restriction of 10 mg twice-daily dose in patients at high risk of pulmonary embolism while safety review is ongoing.
- Magnesium sulfate: risk of skeletal adverse effects in the neonate following prolonged or repeated use in pregnancy.

- **Yellow Card: please help to reverse the decline in reporting of suspected adverse drug reactions**. Covered in the body of the newsletter – see above.

June 2019 (click here for June's Drug Safety Update)

- Direct-acting oral anticoagulants (DOACs): increased risk of recurrent thrombotic events in patients with antiphospholipid syndrome.
- GLP-1 receptor agonists: reports of diabetic ketoacidosis when concomitant insulin was rapidly reduced or discontinued.
- Lartruvo▼ (olaratumab): withdrawal of the EU marketing authorisation due to lack of efficacy.
- Oral retinoid medicines▼: revised and simplified pregnancy prevention educational materials for healthcare professionals and women.

July 2019 (click here for July's Drug Safety Update)

- Febuxostat (Adenuric): increased risk of cardiovascular death and all-cause mortality in clinical trial in patients with a history of major cardiovascular disease.
- Tocilizumab (RoActemra): rare risk of serious liver injury including cases requiring transplantation.

- **Rivaroxaban (Xarelto▼): reminder that 15 mg and 20 mg tablets should be taken with food.** Covered in the body of the newsletter – see above.

The PSNC's patient safety information page contains a list of patient safety alerts, advice and guidance and MHRA monthly drug safety updates and is useful as a quick reference guide for pharmacy teams to check that they are aware of all these and have taken appropriate action when required.

If you have any feedback, suggestions or wish to include anything in our next newsletter please email info@cpwy.org. Thank you